REMARKS

Claims 16, 17, and 21 – 26 are under examination. In the present response, reference to the specification is made using the paragraph numbers of published US Patent Application 2006/0147458 (SN 10/547,207).

1. Claim amendments

Support for the amendments to claim 17 is found in the specification as filed, e.g., at paragraphs 0001, 0002, 0012. Claim 26 has been amended to independent form.

2. Written Description

Claims 16, 17 and 21-25 stand rejected as failing to comply with the written description requirement of 35 USC 112, first paragraph. Applicants respectfully traverse this rejection.

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date, he or she was in possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). However "how the specification accomplishes this is not material." *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976). The applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, as long as the disclosure "clearly allow[s] persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

Thus the disclosure as originally filed need not provide "*in haec verba* support for the claimed subject matter at issue". *Purdue Pharma L.P. v. Faulding Pharmaceutical Co.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). The subject matter of the claims need not be described identically or literally for the application to satisfy the written description requirement. *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983). Rather, "the written description requirement is satisfied by the patentee's disclosure of 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.'" *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

The Office Action states that "the specification does not appear to provide an adequate written description for all nucleic acid molecules having 'a level of nucleotide identity of less than 85% in comparison with the non-repeat region of SEQ ID NO:16' because there is a lack of sufficient written description to support the claimed genus of nucleic acid molecules." Specifically, the Office Action states (paragraph 9) that:

> There is no description of structural or functional features that identify the 'non-repeat region' of a nucleic acid. The 'non-repeat region' of SEQ ID NO:16 is not defined in the specification , therefore one of ordinary skill in the art would be unable to identify other nucleic acid molecules that have a 'level of identity of less than 85% with the non-repeat region of SEQ ID NO:16'. Without such critical identifying features, one skilled in the art would not be able to recognize other species/members of the genus of nucleic acid molecules.

Applicants respectfully disagree. The specification clearly states that the present invention relates to "novel nucleic acid constructs, useful in nucleic acid vaccination protocols for the treatment and prophylaxis of MUC-1 expressing tumours" and that "(i)n particular, the nucleic acid is DNA and the DNA constructs comprise a gene encoding a MUC-1 derivative optionally devoid of all the perfect repeats (paragraph 0001, underlining added). The specification further states that "(i)n one embodiment, the nucleic acid encodes for a MUC-1 derivative as described above devoid of any repeat (both perfect and imperfect) units" (paragraph 0012, underlining added).

At paragraph 0002, the specification states that MUC-1 protein "consists of a cytoplasmic tail, a transmembrane domain and a variable number of tandem repeats of a 20 amino acid motif (herein termed the VNTR monomer, it may also be known as the VNTR epitope, or the VNTR repeat) containing a high proportion of proline, serine and threonine residues. The number of repeats is variable due to genetic polymorphism at the MUC-1 locus, and most frequently lies within the range 30-100". Accordingly, the specification describes the MUC-1 protein as containing a repeat region, as well as other regions. One of ordinary skill in the art would recognize that reference to a "non-repeat region" meant just that – the region of the protein other than the VNTR region. As the DNA of the invention encodes a MUC-1 construct, it would further be clear to one skilled in the art that the "non-repeat region" of the DNA was that region encoding the non-repeat region of the encoded protein.

Independent claim 17 has been amended above to more particularly point this out. Withdrawal of the present rejection is respectfully requested.

3. Objection to claim 26

Claim 26 has been amended to independent form, thus obviating the present objection.

4. Conclusion

Applicants respectfully request examination of this application in view of the comments herein. If the Examiner believes that a telephonic interview would expedite prosecution, the Examiner is invited to contact attorney Virginia G. Campen at (919) 483-1012. Applicants reserve the right to prosecute, in one or more patent applications, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification.

Respectfully submitted,

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